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iv. Chemical Manipulation. Another approach to reducing tar while maintaining adequate nicotine for the smoker is to alter the chemistry of tobacco smoke in a manner that increases the transfer of nicotine to the smoker. As discussed above, BATCO did work in this area in the 1960's, which suggested that increasing the percentage of "extractable nicotine" delivered to the smoker resulted in "nicotine reaching the brain more quickly."⁶⁵⁷

BATCO's research and development efforts continued in the 1970's and 1980's. In a 1976 research conference, BATCO researchers discussed how the use of a filter additive PEI or "alkali treatment" could "maintain normal nicotine reaction for the smoker while actually reducing the amount of nicotine per cigarette":

A second approach . . . is to aim at a lower smoke production per cigarette (i.e. lower tar) while maintaining "normal" nicotine. Work along these lines is already going on. *A further modification of this approach is to maintain normal nicotine reaction for the smoker while actually reducing the total amount of nicotine per cigarette.* It is believed that this can be done, e.g. by the use of P.E.I. or by alkali treatment of tobacco stems.⁶⁵⁸

Similar observations were made at other research conferences. In 1978, for instance, BATCO researchers stated: "With conventional cigarettes, the transfer of nicotine to the smoker from the tobacco has very low efficiency. Potentially, therefore, *opportunities exist for very big savings in tobacco if this low efficiency can be greatly increased.*"⁶⁵⁹

⁶⁵⁷ BATCO, *Further Work on 'Extractable' Nicotine* (1966), at BW-W2-11621. See AR (Vol. 62 Ref. 308).

⁶⁵⁸ Morini HA (BATCO), *Cigarettes with Health Reassurance* (1976), at 1 (emphasis added). See AR (Vol. 27 Ref. 380).

⁶⁵⁹ Notes on BATCO Group R&D Conference at Sydney, Australia (Mar. 1978), at 4 (emphasis added). See AR (Vol. 26 Ref. 367).

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This would not be an “opportunity” if the company did not recognize that nicotine was the essential active ingredient intended to be delivered.

In 1982, BATCO researchers urged that a design objective for new products should be “to enhance or maximise sensory and pharmacological sensations, i.e., ‘to make the smoke work harder’ so as to achieve maximum sensation at a given delivery level.”⁶⁶⁰ And in 1984, BATCO researchers discussed a study in which “*experimental cigarettes . . . will . . . be used to improve the efficient use of smoke nicotine through pH modification.*”⁶⁶¹

v. “Elasticity” Technologies. A third approach to lowering tar while maintaining an adequate nicotine delivery is to increase the “elasticity” of cigarettes. “Elasticity” refers to the ability of a cigarette, whatever its nicotine yield as measured by a smoking machine, to deliver enough smoke to permit a smoker to obtain the nicotine the smoker needs. The elasticity of a cigarette can be increased, for instance, by placing ventilation holes in the filter. These holes allow fresh air to be pulled into the smoking machine during inhalation, thereby diluting the smoke and reducing the measured yields. However, the holes can be blocked by smokers’ fingers or lips, allowing the smoker to obtain more nicotine than the machine measured delivery. *See* 60 FR 41716–41718. Brown & Williamson and BATCO sought to develop elasticity technologies. During a 1983 BATCO conference, BATCO researchers observed that “[e]lasticity can be designed

⁶⁶⁰ Minutes of BATCO Research Conference at Montebello, Canada (Aug. 30-Sep. 3, 1982), at 3 (emphasis added). *See* AR (Vol. 179 Ref. 2082).

⁶⁶¹ BATCO, *Proposed Revisions for 1985-1987* (Sep. 1984), at 1-2 (emphasis added). *See* AR (Vol. 26 Ref. 369-1).

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into a cigarette using tobacco blend and pressure drop components.”⁶⁶² A year later, at a 1984 conference, BATCO researchers elaborated:

Compensation by modifying smoking regime . . . is a topic which is being explored . . . and *this includes designing products which aid smoker compensation.*

The marketing policy concerning this type of product is not clear but it is believed it will depend largely on the degree of elasticity in the design and how overtly this elasticity is achieved. *The consensus is that small improvements in elasticity which are less obvious, visually or otherwise is likely to be an acceptable route.*⁶⁶³

Taken together, Brown & Williamson and BATCO’s product research and development efforts exhibit a sustained focus on nicotine over the course of three decades. The companies recognized through their research that significant marketing opportunities existed for cigarettes that reduced tar deliveries but maintained nicotine deliveries at levels high enough to satisfy smokers’ “inner need” for nicotine. They then developed a broad range of techniques for enhancing nicotine deliveries. These extensive efforts are evidence of a “design” or “plan” to manipulate and control nicotine deliveries to provide a pharmacologically active dose of nicotine.

d. Other Cigarette Manufacturers’ Product Research and Development Efforts

i. American Tobacco Company. The American Tobacco Company

(American Tobacco) also conducted extensive research and development on ways to increase and optimize nicotine deliveries. In 1969, for instance, the company

⁶⁶² BATCO, *Smoking Behavior Conference: Overview* (1983), at BW-W2-03292. See AR (Vol. 27 Ref. 392).

⁶⁶³ Proceedings of BATCO Group R&D Smoking Behaviour-Marketing Conference, Session III (Jul. 9-12, 1984), at 55 (emphasis added). See AR (Vol. 27 Ref. 391).

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manufactured Lucky Strike cigarettes enriched with a nicotine salt (nicotine malate) and sold them in the Seattle market.⁶⁶⁴

In 1974, the company's manager of new products, R. M. Irby, wrote to the vice president of manufacture and leaf, J. B. McCarthy, to summarize "our current knowledge regarding increasing the nicotine content of reconstituted tobacco."⁶⁶⁵ Irby's memorandum stated that nicotine in reconstituted tobacco could be increased either by adding "Compound W," a code name for nicotine, to the reconstituted tobacco or by replacing "the lower nicotine-containing leaf components such as Turkish . . . with high nicotine tobacco such as Malawi sun-cured scrap (5% nicotine)."⁶⁶⁶

Three years later, American Tobacco researchers wrote a memorandum describing "suggested" ways of increasing the nicotine/tar ratio in cigarettes. The methods included the "addition of ammonia salts . . . to tobacco, which on smoking would free the ammonia and thereby cause an increase in nicotine transfer to the smoke."⁶⁶⁷

By 1980, American Tobacco was conducting experiments on this idea by adding a salt (potassium carbonate) to its Tareyton blend. According to the research memorandum describing the experiment, "[s]ince most nicotine in tobacco is a non-volatile salt, *it was*

⁶⁶⁴ Letter to Waxman HA, on behalf of the American Tobacco Company (Oct. 14, 1994), at 3. See AR (Vol. 26 Ref. 355).

⁶⁶⁵ Irby RM Jr. (American Tobacco), *Nicotine Content of Reconstituted Tobacco* (Jun. 5, 1974), at 1. See AR (Vol. 26 Ref. 357-3).

⁶⁶⁶ *Id.* at 1-2.

⁶⁶⁷ Pederson PM (American Tobacco), *A Study of the Nicotine to Tar Ratio* (Apr. 18, 1977), at 4. See AR (Vol. 26 Ref. 365).

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*thought that a greater transfer would take place if the tobacco was made basic causing the nicotine to volatilize when the cigarette is smoked.”*⁶⁶⁸

Other efforts by American Tobacco to increase the amount of nicotine delivered by its cigarettes are described in the Jurisdictional Analysis. See 60 FR 41675–41677. These efforts show that like Philip Morris, RJR, and Brown & Williamson, American Tobacco has designed and planned ways to enhance nicotine deliveries to smokers.

ii. Lorillard Tobacco Company. Like the other cigarette manufacturers, the Lorillard Tobacco Company developed knowledge about numerous ways to manipulate and control nicotine deliveries. For instance, in a 1975 presentation, Alexander Spears, the vice chairman and chief operating officer of Lorillard, stated that “[t]hrough [a] combination of . . . variables, . . . it is possible to manipulate the yield of nicotine from about .1 mg to 4 mg per cigarette.”⁶⁶⁹ The variables cited by Spears as controlling nicotine deliveries included “the nicotine content of the tobacco”; “[the] porosity of the wrapper and/or ventilation at the filter”; “the affinity of the filter material for nicotine, particularly as a function of smoke pH”; and “plant genetics.”⁶⁷⁰

In a 1981 paper on tobacco leaf blending, Spears further described “*the ways in which higher nicotine levels can be achieved.*”⁶⁷¹ Spears explained that nicotine

⁶⁶⁸ Bodenhamer NL (American Tobacco), *Leaf Services Monthly Report for June* (Jun. 30, 1980) (emphasis added). See AR (Vol. 27 Ref. 385)

⁶⁶⁹ Spears AW (Lorillard Tobacco Co.), *Factors Affecting Smoke Delivery of Nicotine and Carbon Monoxide*, presented at the 1975 Symposium-Nicotine and Carbon Dioxide (Nov. 17-18, 1975), in Symposium Proceedings-1, at 13 (emphasis added). See AR (Vol. 27 Ref. 395a).

⁶⁷⁰ *Id.*

⁶⁷¹ Spears AW, Jones ST (Lorillard Tobacco Co.), Chemical and Physical Criterias for Tobacco Leaf of Modern Day Cigarettes, *Recent Advances in Tobacco Science*, Oct. 6-9, 1981;7:19-39, at 23. See AR (Vol. 26 Ref. 373-1).

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concentrations of tobaccos vary widely, from 3.65% nicotine in upper-stalk Burley tobacco and 3.26% in upper-stalk flue-cured tobacco to 0.95% in Oriental tobacco and 0.85% in stem-sheet or reconstituted tobacco. According to Spears, “[h]igher nicotine levels can be achieved by decreasing Oriental and the stem and tobacco sheet and increasing the Burley and upper stalk positions of both the Flue-cured and the Burley tobacco.”⁶⁷² He further observed that “current research is directed toward increasing the nicotine levels while maintaining or marginally reducing the ‘tar’ deliveries.”⁶⁷³

The administrative record thus reveals that the cigarette manufacturers have consistently focused their product research and development efforts on developing methods to maintain or enhance nicotine deliveries. These activities are remarkable for their sustained duration and for the fact that each cigarette manufacturer independently acquired similar capabilities to manipulate and control nicotine deliveries. This again demonstrates the central role of nicotine delivery in the design of cigarettes.

e. Filter and Paper Suppliers’ Product Research and Development Efforts

The filter and paper suppliers for cigarette manufacturers also developed products to enhance nicotine deliveries, including methods for “increasing nicotine delivery *without* changing tar delivery”⁶⁷⁴ and for “alter[ing] cigarette nicotine delivery *independently* of tar

⁶⁷² *Id.* at 24 (emphasis added).

⁶⁷³ *Id.* at 31 (emphasis added).

⁶⁷⁴ Selke WA, Making the cigarette do just what you want it to do, *Journal Tobacco International*, 1983:12 (emphasis added). See AR (Vol. 102 Ref. 896).

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delivery.”⁶⁷⁵ These efforts are not direct evidence of the manufacturers’ intent, because the product development was conducted by suppliers, rather than the manufacturers themselves. Nevertheless, the suppliers’ efforts corroborate the Agency’s finding that the cigarette manufacturers seek the capability to enhance nicotine deliveries in low-tar cigarettes. They show that the suppliers understood manufacturers to be interested in acquiring products that would enable the manufacturers to selectively remove more tar than nicotine from cigarette smoke.

To develop products with enhanced nicotine deliveries, the filter and paper suppliers altered the filtration and ventilation systems in cigarettes. Filters are used to trap smoke particles before they enter the mouths of smokers. Ventilation technologies draw air into the cigarette through holes in the filter or through porous cigarette paper, diluting the smoke. The suppliers found that these systems could be manipulated to selectively remove more tar than nicotine, thereby increasing the nicotine/tar ratio in the smoke.

Documents in the administrative record describe several of the methods developed for increasing nicotine delivery relative to tar. According to one report, “[s]imply changing the location of the vents in a . . . filter has a measurable effect on the cigarette performance,” with “the nicotine content [being] . . . greatest when the vents were positioned where the tobacco and filter were joined.”⁶⁷⁶ The same effect could be achieved by perforating the cigarette paper. One report found that “[i]ncreasingly porous

⁶⁷⁵ Lee BM (Eastman Kodak Company), *Modification of Nicotine to Tar Ratio in Cigarette Smoke*, 42nd Tobacco Chemists’ Research Conference, Lexington, Kentucky (Oct. 2-5, 1988), at 33 (emphasis added). See AR (Vol. 639 Ref. 2).

⁶⁷⁶ Kiefer JE, *Ventilated Filters and Their Effect on Smoke Composition*, *Recent Advances in Tobacco Science* (1979), at 79. See AR (Vol. 28 Ref. 465).

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perforated papers . . . *selectively increase nicotine*. . . .”⁶⁷⁷ Research by a tobacco company confirmed the influence of paper design on tar and nicotine deliveries, finding that “tar/nicotine ratios are determined primarily by paper permeability; high permeability produces the lowest tar/nicotine ratios.”⁶⁷⁸ A low tar/nicotine ratio is mathematically equivalent to a high nicotine/tar ratio.

Other reports have shown that cigarettes designed with increased ventilation and less filtration will “increas[e] nicotine delivery without changing tar delivery;”⁶⁷⁹ and that the use of additives to increase the pH of the filter will alter cigarette nicotine delivery independently of tar delivery, increasing the nicotine/tar ratio by up to 15%.⁶⁸⁰

f. These Product Research and Development Efforts Were Undertaken for Commercial Reasons

The cigarette manufacturers do not generally dispute that they engaged in the product research and development activities described above. Instead, they argue that their research on increasing or maintaining nicotine delivery while lowering tar was largely in response to “government” initiatives. In support of this claim, these comments refer to

⁶⁷⁷ Owens Jr. WF (Ecusta Paper and Film Group), *Effect of Cigarette Paper on Smoke Yield and Composition*, 32d Tobacco Chemists’ Research Conference, Montreal, Canada (1978) (emphasis added). See AR (Vol. 639 Ref. 2).

⁶⁷⁸ McMurtrie A, Littringer EF, and Wu DT, *Cigarette Paper Effects on Tar/Nicotine and CO/Tar Ratios*, 35th Tobacco Chemists’ Research Conference, Winston-Salem, North Carolina (1981). See AR (Vol. 639 Ref. 2).

⁶⁷⁹ Selke WA, Making the cigarette do just what you want it to do, *Journal Tobacco International* 1983:12. See AR (Vol. 102 Ref. 896).

Browne CL (Hoechst Celanese), *The Design of Cigarettes*, at 72. See AR (Vol. 27 Ref. 399).

⁶⁸⁰ Lee BM (Eastman Kodak Company), *Modification of Nicotine to Tar Ratio in Cigarette Smoke*, 42nd Tobacco Chemists’ Research Conference, Lexington, Kentucky (Oct. 2-5, 1988), at 33. See AR (Vol. 639 Ref. 2).

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a few sentences in a 1981 report of the U.S. Surgeon General, the recommendation of a scientist at NIH in 1976, and a few scattered articles from nongovernment researchers beginning in 1973. The comments offer no evidence from company documents to show that any part of the industry's extensive research on increasing nicotine delivery from low-tar cigarettes was actually motivated by the cited "initiatives."

The evidence in the administrative record also fails to support the industry's claims. The large number of internal tobacco company documents available to FDA indicates that the companies' product research and development was conducted for commercial reasons. Philip Morris, for instance, stated that "the rationale" for its research and development efforts "rests on the premise that such knowledge will strengthen Philip Morris R&D capability in developing new and improved smoking products."⁶⁸¹

The driving force behind the efforts to enhance nicotine delivery in low-tar products was the industry's knowledge that people use tobacco for nicotine and that below a certain nicotine level, the motivation for tobacco use, and the market for tobacco products will disappear. RJR researchers knew in the 1970's that "a zero nicotine cigarette . . . fails to provide the ultimate satisfaction in the lungs;" hence they recommended "*maintaining the nicotine as high as possible*" in low-tar cigarettes.⁶⁸² Similarly, a 1976 BATCO "Smoking Behaviour" conference report shows that BATCO was aware of the need to maintain adequate nicotine deliveries, stating that "the 'benefits' of smoking appear to be related to nicotine, [and] we can infer that the 'benefits' of

⁶⁸¹ Dunn WL, *Plans and Objectives—1979* (Dec. 6, 1978), in 141 Cong. Rec. H7669 (daily ed. Jul. 25, 1995). See AR (Vol. 14 Ref. 175a).

⁶⁸² Senkus M (R.J. Reynolds Tobacco Co.), *Some Effects of Smoking* (1976/1977), at 9, 10 (emphasis added). See AR (Vol. 700 Ref. 593).

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smoking might disappear if cigarettes with low levels of nicotine became the norm.”⁶⁸³

Likewise, a 1972 Philip Morris presentation indicates that Philip Morris knew that cigarettes with inadequate levels of nicotine would not be purchased by smokers.⁶⁸⁴

Moreover, the industry’s research on selectively increasing or maintaining nicotine while lowering tar cannot be attributed to government initiatives because it began before the earliest government “initiative” cited by the comments. For example, as noted in section II.C.3.c.i. above, Brown & Williamson was developing “ways of obtaining maximum nicotine for minimum tar” at least as early as 1965⁶⁸⁵—well before the 1976 NIH and the 1981 Surgeon’s General documents cited by the industry. Similarly, Philip Morris was working on increasing nicotine levels in relation to tar as early as 1970, when it began experimentally altering the nicotine/tar ratio of Marlboro cigarettes by “reduc[ing] the tar delivery incrementally . . . and increas[ing] the nicotine delivery incrementally by adding a nicotine salt.”⁶⁸⁶ Thus, the industry was plainly developing low-tar, enhanced-nicotine products before any of the cited “government initiatives.”

Finally, FDA notes that to the extent that the industry accepted the recommendations of outside researchers who suggested the development of low-tar, high-nicotine products, those recommendations were based on the researchers’ conclusion that

⁶⁸³ Minutes of BATCO Group R&D Conference on Smoking and Behaviour at Southampton, England (Oct. 11-12, 1976), at 4. See AR (Vol. 27 Ref. 376).

⁶⁸⁴ Dunn WL (Philip Morris Inc.), *Motives and Incentives in Cigarette Smoking* (1972), at 4 (emphasis added). See AR (Vol. 12 Ref. 133).

⁶⁸⁵ Griffith RB (BATCO), *Report to Executive Committee* (Jul. 1, 1965), at 2. See AR (Vol. 27 Ref. 377).

⁶⁸⁶ Eichorn PA, Dunn WL (Philip Morris Inc.), *Quarterly Report of Projects 1600 and 2302—Oct. 1-Dec. 31, 1970* (Dec. 31, 1970), in 141 Cong. Rec. H8128 (daily ed. Aug. 1, 1995). See AR (Vol. 27 Ref. 376).